



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2021
EMA/76805/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): quinapril

Procedure No.: PSUSA/00002591/202104



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Accupril 10 mg Filmtabletten	not available	BE150954	PFIZER S.A. (BELGIUM)	BE
Accupril 10 mg Filmtabletten	not available	2003027114	PFIZER S.A. (BELGIUM)	LU
Accupril 20 mg Filmtabletten	not available	BE150981	PFIZER S.A. (BELGIUM)	BE
Accupril 20 mg Filmtabletten	not available	2003027115	PFIZER S.A. (BELGIUM)	LU
Accupril 40 mg Filmtabletten	not available	BE150963	PFIZER S.A. (BELGIUM)	BE
Accupril 40 mg Filmtabletten	not available	2003027116	PFIZER S.A. (BELGIUM)	LU
Accupril 5 mg Filmtabletten	not available	BE150972	PFIZER S.A. (BELGIUM)	BE
Accupril 5 mg Filmtabletten	not available	2003027113	PFIZER S.A. (BELGIUM)	LU
Accupril® 10 mg Filmtabletten	not available	23665.01.00	PFIZER PHARMA PFE GMBH	DE
Accupril® 20 mg Filmtabletten	not available	23665.02.00	PFIZER PHARMA PFE GMBH	DE
Accupril® 5 mg Filmtabletten	not available	23665.00.00	PFIZER PHARMA PFE GMBH	DE
ACCUPRIN 10 mg compresse rivestite con film	not available	027217025	PFIZER ITALIA S.R.L.	IT
ACCUPRIN 20 mg compresse rivestite con film	not available	027217102	PFIZER ITALIA S.R.L.	IT
ACCUPRIN 20 mg compresse rivestite con film	not available	027217037	PFIZER ITALIA S.R.L.	IT
ACCUPRIN 40 mg compresse rivestite con film	not available	027217090	PFIZER ITALIA S.R.L.	IT
ACCUPRIN 5 mg compresse rivestite con film	not available	027217013	PFIZER ITALIA S.R.L.	IT
ACCUPRO 10 filmom obalené tablety	not available	58/0293/18-S	PFIZER EUROPE MA EEIG	SK
ACCUPRO 10 mg apvalkotās tabletes	not available	99-0548	PFIZER EUROPE MA EEIG	LV
Accupro 10 mg comprimate filmate.	not available	9377/2016/01	PFIZER EUROPE MA EEIG	RO
Accupro 10 mg film-coated tablets	not available	PA 822/7/2	PFIZER HEALTHCARE IRELAND	IE
Accupro 10 mg filmtabletta	not available	OGYI-T-4163/02	PFIZER KFT.	HU
ACCUPRO 10 mg plėvele dengtos tabletės	not available	LT/1/2000/0234/003	PFIZER EUROPE MA EEIG	LT
ACCUPRO 10 mg plėvele dengtos tabletės	not available	LT/1/2000/0234/004	PFIZER EUROPE MA EEIG	LT
ACCUPRO 10 mg potahované tablety	not available	58/312/91-B/C	PFIZER, SPOL. S R.O.	CZ

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ACCUPRO 10 mg tabletti, kalvopäällysteinen	not available	10771	PFIZER OY	FI
ACCUPRO 10, 10 mg, tabletki powlekane	not available	R/7070	PFIZER EUROPE MA EEIG	PL
ACCUPRO 20 filmom obalené tablety	not available	58/0294/18-S	PFIZER EUROPE MA EEIG	SK
ACCUPRO 20 mg apvalkotās tabletes	not available	99-0549	PFIZER EUROPE MA EEIG	LV
Accupro 20 mg comprimate filmate.	not available	9378/2016/01	PFIZER EUROPE MA EEIG	RO
Accupro 20 mg film-coated tablets	not available	PA 822/7/3	PFIZER HEALTHCARE IRELAND	IE
Accupro 20 mg filmtabletta	not available	OGYI-T-4163/03	PFIZER KFT.	HU
ACCUPRO 20 mg plėvele dengtos tabletės	not available	LT/1/2000/0234/006	PFIZER EUROPE MA EEIG	LT
ACCUPRO 20 mg plėvele dengtos tabletės	not available	LT/1/2000/0234/005	PFIZER EUROPE MA EEIG	LT
ACCUPRO 20 mg plėvele dengtos tabletės	not available	LT/1/2000/0234/007	PFIZER EUROPE MA EEIG	LT
ACCUPRO 20 mg potahované tablety	not available	58/312/91-C/C	PFIZER, SPOL. S R.O.	CZ
ACCUPRO 20 mg tabletti, kalvopäällysteinen	not available	10772	PFIZER OY	FI
ACCUPRO 20, 20 mg, tabletki powlekane	not available	R/7071	PFIZER EUROPE MA EEIG	PL
Accupro 40 mg film-coated tablets	not available	PA 822/7/4	PFIZER HEALTHCARE IRELAND	IE
ACCUPRO 40 mg plėvele dengtos tabletės	not available	LT/1/2000/0234/001	PFIZER EUROPE MA EEIG	LT
ACCUPRO 40, 40 mg, tabletki powlekane	not available	10801	PFIZER EUROPE MA EEIG	PL
ACCUPRO 5 filmom obalené tablety	not available	58/0312/91-C/S	PFIZER EUROPE MA EEIG	SK
Accupro 5 mg comprimate filmate.	not available	9376/2016/01	PFIZER EUROPE MA EEIG	RO
Accupro 5 mg film-coated tablets	not available	PA 822/7/1	PFIZER HEALTHCARE IRELAND	IE
Accupro 5 mg filmtabletta	not available	OGYI-T-4163/01	PFIZER KFT.	HU
ACCUPRO 5 mg plėvele dengtos tabletės	not available	LT/1/2000/0234/002	PFIZER EUROPE MA EEIG	LT
ACCUPRO 5 mg potahované tablety	not available	58/312/91-A/C	PFIZER, SPOL. S R.O.	CZ

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ACCUPRO 5 mg tabletti, kalvopäällysteinen	not available	10770	PFIZER OY	FI
ACCUPRO 5, 5 mg, tabletki powlekane	not available	R/7069	PFIZER EUROPE MA EEIG	PL
Accupro® 10 10 mg Filmtabletten	not available	17443.01.00	PFIZER PHARMA GMBH	DE
Accupro® 10 mg Filmtabletten	not available	1-19361	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Accupro® 20 20 mg Filmtabletten	not available	17443.02.00	PFIZER PHARMA GMBH	DE
Accupro® 20 mg Filmtabletten	not available	1-19363	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Accupro® 5 5 mg Filmtabletten	not available	17443.00.00	PFIZER PHARMA GMBH	DE
Accupro® 5 mg Filmtabletten	not available	1-19359	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Accupron	not available	13096	PFIZER HELLAS, A.E.	CY
Accupron	not available	13095	PFIZER HELLAS, A.E.	CY
Accupron	not available	41131/10/31-05-2011	PFIZER HELLAS, A.E.	GR
Accupron	not available	41129/10/31-05-2011	PFIZER HELLAS, A.E.	GR
Accupron	not available	41126/10/31-05-2011	PFIZER HELLAS, A.E.	GR
Acequin 20 mg compresse rivestite con film	not available	027230097	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Acequin 20 mg compresse rivestite con film	not available	027230034	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Acequin 5 mg compresse rivestite con film	not available	027230010	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
ACUITEL 20 mg, comprimé enrobé sécable	not available	34009 560 069 6 0	PFIZER HOLDING FRANCE	FR
ACUITEL 20 mg, comprimé enrobé sécable	not available	34009 372 964 1 0	PFIZER HOLDING FRANCE	FR
ACUITEL 20 mg, comprimé enrobé sécable	not available	34009 331 722 3 7	PFIZER HOLDING FRANCE	FR
ACUITEL 20 mg, comprimé enrobé sécable	not available	34009 560 070 4 2	PFIZER HOLDING FRANCE	FR
ACUITEL 20 mg, comprimé enrobé sécable	not available	34009 331 724 6 6	PFIZER HOLDING FRANCE	FR

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ACUITEL 5 mg, comprimé enrobé sécable	not available	34009 372 963 5 9	PFIZER HOLDING FRANCE	FR
ACUITEL 5 mg, comprimé enrobé sécable	not available	34009 331 725 2 7	PFIZER HOLDING FRANCE	FR
ACUITEL 5 mg, comprimé enrobé sécable	not available	34009 331 726 9 5	PFIZER HOLDING FRANCE	FR
ACUITEL 5 mg, comprimé enrobé sécable	not available	34009 560 072 7 1	PFIZER HOLDING FRANCE	FR
ACUITEL 5 mg, comprimé enrobé sécable	not available	34009 560 071 0 3	PFIZER HOLDING FRANCE	FR
Acuprel 20 mg comprimidos recubiertos con película	not available	59.082	PFIZER, S.L.	ES
Acuprel 40 mg comprimidos recubiertos con película	not available	61.710	PFIZER, S.L.	ES
Acuprel 5 mg comprimidos recubiertos con película	not available	59.081	PFIZER, S.L.	ES
Acupril 20 mg Comprimidos revestidos por película	not available	4591087	LABORATÓRIOS PFIZER, LDA.	PT
Acupril 20 mg Comprimidos revestidos por película	not available	2195683	LABORATÓRIOS PFIZER, LDA.	PT
Acupril 20 mg Comprimidos revestidos por película	not available	2195584	LABORATÓRIOS PFIZER, LDA.	PT
Acupril 40 mg Comprimidos revestidos por película	not available	5829684	LABORATÓRIOS PFIZER, LDA.	PT
Acupril 40 mg Comprimidos revestidos por película	not available	2504785	LABORATÓRIOS PFIZER, LDA.	PT
Ectren 20 mg comprimidos recubiertos con película	not available	59.191	LABORATORIOS MENARINI, S.A.	ES
Ectren 40 mg comprimidos recubiertos con película	not available	61.733	LABORATORIOS MENARINI, S.A.	ES
LIDALTRIN 20 mg comprimidos recubiertos con película	not available	59.203	LACER S.A.	ES
LIDALTRIN 40 mg comprimidos recubiertos con película	not available	61.672	LACER S.A.	ES
LIDALTRIN 5 mg comprimidos recubiertos con película	not available	59.202	LACER S.A.	ES

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
QUINAZIL 20 mg compresse rivestite con film	not available	027225034	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
QUINAZIL 20 mg compresse rivestite con film	not available	027225097	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
QUINAZIL 5 mg compresse rivestite con film	not available	027225010	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Акупро 10 mg филмирани таблетки	not available	20010922	PFIZER EUROPE MA EEIG	BG
Акупро 20 mg филмирани таблетки	not available	20010923	PFIZER EUROPE MA EEIG	BG